

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,)
)
Plaintiff,)
)
v.)
) C.A. No.: 1:19-cv-1804-CFC
EUROFINS VIRACOR, INC.,)
)
Defendant,)
)
and)
)
THE BOARD OF TRUSTEES OF)
THE LELAND STANFORD)
JUNIOR UNIVERSITY)
)
Nominal Defendant.)

**EUROFINS VIRACOR, INC.'S RESPONSES TO CAREDX, INC.'S
ADDITIONAL MATERIAL FACTS**

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Dated: August 7, 2020

Eurofins Viracor, Inc.’s (“Eurofins”) responds to CareDx, Inc.’s alleged “Additional Material Facts” as set forth below. This response is supported by Eurofins’s concurrently filed Reply Brief in Support of Motion for Summary Judgment That the Asserted Claims of U.S. Patent No. 8,703,652 Are Invalid Under 35 U.S.C. § 101 (“Reply”), which sets forth Eurofins’s explanations and bases for responding to these “facts.”

| | “Alleged Material Fact” | Eurofins’s Response |
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| 1 | The patents acknowledge that since 1998, it was known in the art that donor cell-free DNA could serve as an indicator of organ transplant rejection. | Immaterial: ¹ <ul style="list-style-type: none"> • Reply at 2-5. |
| 2 | The patents acknowledge that there were numerous attempts to devise methods that would be able to use donor cell-free DNA to monitor for organ rejection prior to 2009. | Immaterial: <ul style="list-style-type: none"> • Reply at 2-5. |

¹ Regarding Eurofins’s responses on the ground that the alleged facts are immaterial: CareDx fails to explain in its opposition brief how any of these “alleged material facts” are material, and fails to include any citation to them in its opposition brief. For that reason alone, CareDx’s additional “facts” should be ignored as immaterial. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (instructing that “substantive law will identify which facts are material,” and “[o]nly disputes over facts that might affect the outcome of the suit under the governing law will [] preclude [] summary judgment”).

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| 3 | The patents acknowledge that one type of prior art attempt at using donor cell-free DNA to monitor for organ rejection was limited to the special case of females receiving organs from males. | Immaterial: <ul style="list-style-type: none">Reply at 2-5. |
| 4 | The patents acknowledge that another type of prior art attempt at using donor cell-free DNA to monitor for organ rejection was limited by the inability to distinguish HLA alleles between all donors and recipients. | Immaterial: <ul style="list-style-type: none">Reply at 2-5. |
| 5 | The patents acknowledge that as of November 6, 2009, there was a recognized need in the art for methods of noninvasive detection of organ transplant rejection. | Immaterial: <ul style="list-style-type: none">Reply at 2-5. |
| 6 | In 2008, researchers stated in a published article that the use of cell-free DNA for organ transplant rejection was “impractical.” | Immaterial: <ul style="list-style-type: none">F0145 at 144:5-22; F0148 at 147:3-20; F0149 at 148:7-12; F0154-F0155 at 153:19-154:3; F0155-F0156 at 154:16-155:15;F0295-F0296;Reply at 2-5, 9. |

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| 7 | In 2009, there was no known universal approach to noninvasive detection of organ transplant rejection in transplant patients that utilized donor cell-free DNA. | <p>Immaterial, unsupported, and contradicted by CareDx's expert's testimony:²</p> <ul style="list-style-type: none"> • A72-100, ¶129-168; • F0242 at 241:8-22; F0243-F0244 at 242:20-243:6; F0248-F0249 at 247:19-248:4; F0250 at 249:4-14; F0252 at 251:6-14; F0253-F0254 at 252:13-253:5, 253:13-19; • Reply at 2-5, 9-10. |
| 8 | The claims of the asserted patents are not directed to the correlation between donor cell-free DNA and transplant rejection because the correlation was an acknowledged feature of the prior art. | <p>This is a legal conclusion and not a fact.³</p> <p>To the extent this is construed as a fact, it is immaterial:</p> <ul style="list-style-type: none"> • Reply at 2-5. |

² Regarding Eurofins's responses on grounds that the alleged material facts are unsupported and contradicted by the record: *See, e.g., Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986) (“Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial.”); *Schoch v. First Fidelity Bancorporation*, 912 F.2d 654, 657 (3d Cir. 1990) (a nonmoving party may not rely on “unsupported allegations in his memorand[a] and pleadings . . . to repel summary judgment”); Fed. R. Civ. P. 56(e)(2) (to avoid summary judgment the nonmoving party may not rest on mere allegations or denials of her pleading).

³ Regarding Eurofins's responses on the ground that the alleged “facts” are legal conclusions, not facts: *See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 749 (Fed. Cir. 2019), cert. denied, 140 S. Ct. 855, 205 L. Ed. 2d 460 (2020); *see also* C1260 at 9:5-7 (CareDx’s counsel admitting that Step One is a “purely legal issue” and “[t]here are no factual components to it”).

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| 9 | The asserted patents describe the putative invention as an improvement on how to measure cell-free DNA for monitoring organ rejection. | <p>Immaterial:</p> <ul style="list-style-type: none"> • Reply at 4-5. |
| 10 | In 2009, no published literature disclosed the use of the specific laboratory techniques recited in the claims of the asserted patents in the context of organ transplant rejection. | <p>Unsupported and contradicted by CareDx's expert's testimony:</p> <ul style="list-style-type: none"> • A72-100, ¶129-168; • F0242 at 241:8-22; F0243-F0244 at 242:20-243:6; F0248-F0249 at 247:19-248:4; F0250 at 249:4-14; F0252 at 251:6-14; F0253-F0254 at 252:13-253:5, 253:13-19; • Reply at 8-10; • Eurofins's CSUF ("Eurofins's CSUF") at UF-13, UF-14, UF-16, UF-17. |
| 11 | In 2009, high-throughput sequencing was not a conventional laboratory technique. | <p>Immaterial, unsupported, and contradicted by the '652 Patent, CareDx's responses to Eurofins's CSUF, D.I. 65 ("CareDx Response to CSUF"), and CareDx's expert's testimony:</p> <ul style="list-style-type: none"> • B0001 at 5:36-49, 15:1-16:41; • F0104 at 103:20-23; F0105-F0106 at 104:25-105:5; F0109-F0110 at 108:8-109:16; • Reply at 16-19; • CareDx's Response to CSUF, at UF-18, UF-19, UF-22, UF-23, UF-24. |

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| 12 | In 2009, it was not conventional to prepare blood samples containing cell-free DNA. | <p>Immaterial, unsupported, and contradicted by the '652 Patent, CareDx's expert's testimony, and CareDx's Response to CSUF:</p> <ul style="list-style-type: none"> • CareDx's Response to CSUF at UF-11, UF-12, UF-30, UF-31 (asserting that underlying facts are “[u]ndisputed”); • B0001 at 1:14-17, B0012 at 6:57-67, B0014 at 9:4-14, 10:7-12; • F0180 at 179:18-23, F0182 at 181:1-7, F0242 at 241:8-22, F0253-F0254 at 252:13-253:5; • Reply at 14-15. |
| 13 | In 2009, digital PCR was not a conventional alternative to sequencing. | Immaterial to the '652 Patent claims. Digital PCR is not recited in the '652 claims. |
| 14 | In 2009, it was not conventional to develop SNP profiles to detect cell-free DNA. | <p>Unsupported and contradicted by the '652 Patent and CareDx's expert's testimony:</p> <ul style="list-style-type: none"> • B0001 at 7:30-36; 13:40-67; • F0094 at 93:9-15; F0095 at 94:1-25; • Reply at 16-18; • Eurofins's CSUF at UF-6, UF-7, UF-9, UF-15, UF-16, UF-24. |
| 15 | In 2009, it was not conventional to selectively amplify 1,000 SNPs to detect cell-free DNA. | Immaterial to the '652 Patent claims. Selective amplification of 1,000 SNPs is not recited in the '652 Patent claims. |

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| 16 | In 2009, it was not conventional to quantify cell-free DNA. | <p>Unsupported and contradicted by the Patent and CareDx's expert's testimony:</p> <ul style="list-style-type: none"> • B0001 at 15:2-6; 18:56-19:15; • F0185 at 184:1-17; F0253 at 252:13-21; • Reply at 16-19; • Eurofins's CSUF at UF-16, UF-24. |
| 17 | Findings related to the methods described in the asserted patents were published in 2011 in the Proceedings of the National Academy of Sciences. | <p>Immaterial:</p> <ul style="list-style-type: none"> • Reply at 2-5, 8-10. |
| 18 | Dr. Quackenbush's proposed level of ordinary skill in the art is inconsistent with positions he has previously taken and does not reflect the actual level of ordinary skill. | <p>Immaterial:</p> <ul style="list-style-type: none"> • Reply at 10. |
| 19 | The methods recited in the asserted patents, when viewed as a whole, provide an inventive advance over the prior art. | <p>Immaterial. This is also an incorrect legal conclusion, not a fact:</p> <ul style="list-style-type: none"> • Reply at 8-10. |

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Dated: August 7, 2020

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